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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Scott Sullivan & Robert Hess

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Title: PILL PRINTING AND IDENTIFICATION

TECHNOLOGY CENTER 2800

AMENDMENT

Assistant Commissioner for Patents
Washington, DC 20231

Dear Sir;

Responsive to the Office Action dated April 15, 2002, please consider the following:

Claims 1-3, 5-10, 12, 40-50 were rejected under 35 USC 103(a) over Ackley in view of Kraft et al., Shamir and Stafford et al. The rejection is traversed.

The Office Action makes the following assertions (identified in bold on pages 1, 2)

It would have been obvious to print a bar code for identifying information relating to the pill on the surface of the pill.

This is a conclusory statement without making any reference to prior art teachings. As such, the statement fails to substantiate a *prima facie* case of obviousness of the claimed invention in any manner.

Reference to Kraft is cited as evidence that there are plenty information relating to the pill which could be of interest or necessity to a user.

This statement is meaningless since it bears no relationship to the recited claim language of claims 1-3, 5-10, 12, 40-50. The applicant is not claiming the general concept of providing plenty of information relating to the pill that could be of interest or

necessity to a user. As such, the statement fails to substantiate a *prima facie* case for obviousness of the claimed invention in any manner.

Kraft is also disclose the need of product identification including the use of bar codes, bar codes readers, databases, etc.

This statement is meaningless since it bears no relationship to the recited claim language of claims 1-3, 5-10, 12, 40-50. The applicant is not claiming to the inventor of bar codes, bar code readers or databases so showing that Kraft reveals such items is of no consequence to the issue of patentability. As such, the fails to substantiate a *prima facie* case for obviousness of the claimed invention in any manner.

Reference to Shamir is cited as evidence showing it is possible to use of a micro-bar code to label small product other than an IC die/chip.

This statement is meaningless since it bears no relationship to the recited claim language of claims 1-3, 5-10, 12, 40-50. The applicant is not claiming to be the inventor of use of a micro-bar code to small products in general other than an IC die/chip so showing that Shamir reveals such a concept is of no consequence to the issue of patentability. Further a skilled artisan would understand from Shamir that the "small products" it envisions are merely equivalents to IC die/chip, as opposed to each and every conceivable product made by mankind that is of "small" size (whatever the relative term "small" should mean) as the Office Action seemingly envisions. As such, the statement fails to substantiate a *prima facie* case for obviousness of the claimed invention in any manner.

Reference to the Stafford is further cited as evidence showing that it is actually possible to print a bar code on the surface of an object having the approximate shape of a typical pill and/or capsule.

While such a statement seems reasonable, it fails to substantiate the Office Action's position that it would be obvious to modify Ackley by Kraft et al, Shamir and Stafford. Just because Stafford may show it is actually possible to print a bar code on the surface of an object having the approximate shape of a typical pill and/or capsule does not mean the hypothetical combination of patent teachings is rendered obvious. As such, the Office Action fails to make out a *prima facie* case of obviousness. Furthermore, the relationship between such a statement and the recitation of the claim language in each of the claims has been not been shown in the Office Action.

From the comprehensive teachings of the prior art of record, it has been determined that it would have been obvious to provide a bar code on a surface of a pill for the purpose of produce identification thereof. The modification is well within the skill levels and expectations of an ordinary skilled artisan at the time the invention was made.

Such statements clearly rely on impermissible hindsight of the applicant's disclosure. The specific "comprehensive teachings of the prior art of record" as it may pertain to the claimed invention is never revealed in the Office Action. Indeed, no effort at all was made to compare the claim language itself with any of the prior art teachings. In the absence of such a comparison, the finding of obviousness is necessarily unsubstantiated and without justification. Further, the Office Action makes no effort at even identifying what those skill levels are of an ordinary skilled artisan at the time the invention was made.

MPEP 2143.01 provides:

FACT THAT REFERENCES CAN BE COMBINED OR MODIFIED IS NOT SUFFICIENT TO ESTABLISH *PRIMA FACIE* OBVIOUSNESS

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990) (Claims were directed to an apparatus for producing an aerated cementitious composition by drawing air into the cementitious composition by driving the output pump at a capacity greater than the feed rate. The prior art reference taught that the feed means can be run at a variable speed, however the court found that this does not require that the output pump be run at the claimed speed so that air is drawn into the mixing chamber and is entrained in the ingredients during operation. Although a prior art device "may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so." 916 F.2d at 682, 16 USPQ2d at 1432.). See also *In re Fritch*, 972 F.2d 1260, 23 USPQ2d 1780 (Fed. Cir. 1992) (flexible landscape edging device which is conformable to a ground surface of varying slope not suggested by combination of prior art references).

Regarding claim 3, see the discussions above. Specifically, Stafford disclose the concept of having a transparent cover for protecting the inner core 2 and the bar code 15 for being damaged. Following this teaching, it would have been obvious to incorporate the use of a protective layer for protecting the surface of the pill and the bar code from being damaged. The modification is merely a design consideration which would have been well within the skill levels and expectations of an ordinary skilled artisan.

Such is a clear misreading of claim 3. Claim 3 calls for a transparent layer having an inner and outer surface. The bar code is arranged on the inner surface and visible through the transparent layer. In Stafford, the bar code is on the outer surface of a inner core 2 and the inner core 2 is fitted within a transparent shell 3. Since the bar code is not placed on the inner surface of the transparent shell, but rather on the outside surface of the shell 3 and the outside surface of the inner core 3, Stafford does not render obvious claim 3. See Fig. 1 of Stafford and the discussion at col. 6 lines 4-5 and 16-18.

Regarding claim 6-10, 12, 40-50, see the discussions above. Specifically, the various features of the claims, i.e. 2D bar code, PDF 47 bar code, UPC bar code, the step of administering the drug to a user, the step of warning a user based on dosage information, etc. are merely the variations in designs and/or intended applications of a pill product identification system. Without any specific, unexpected result, it would have been obvious to incorporate these features in the system as taught, as has been discussed above. The modifications are merely within the skilled level and expectations of an ordinary skilled artisan.

The claim analysis for claims 6-10, 12, 40-50 fails to properly apply the test for obviousness and thus the rejection warrants withdrawal on this basis alone. Such an analysis clearly is at odds with MPEP 2143, which provides:

2143 Basic Requirements of a *Prima Facie* Case of Obviousness

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaack*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Here, the Office Action fails to even comment on any suggestion or motivation for making the hypothetical combination. In addition, whether or not the four patent documents being applied in the rejection reveal various concepts fails to demonstrate any reasonable expectation of attaining the subject matter recited in the rejected claims. Further, the Office Action provides no claim language analysis with the hypothetical modification of patent teachings and therefore fails to consider all the claim limitations as recited by the rejected claims. The obviousness rejection clearly uses the applicant's disclosure to impermissibly pick and choose various features in the prior art in an effort to yield the present invention. In doing so, the effort blatantly falls short of yielding the claimed subject matter anyway.

In an effort to overcome this deficiency, the Office Action characterizes the subject matter of the rejected claims as "merely the variations in designs and/or intended applications of a pill product identification system". The contention is flawed for many reasons. First, the regulations do not permit an examiner to bypass the *prima facie* case for obviousness by asserting that the claimed invention is merely a variation in design and/or intended application. MPEP 2143. Second, the Office Action's analysis fails to make a comparison between all the claim language and the hypothetical combination of prior art. Third, the patent statutes do not require there be an "specific, unexpected result" for an invention to be patentable and thus the Examiner requirement that such be present is contrary to the regulations. Further, the unexpected result is clearly apparent from each of the rejected claims.

Instead, MPEP 2141 provides:

**STANDARD OF PATENTABILITY TO BE APPLIED
IN OBVIOUSNESS REJECTIONS**

Patent examiners carry the responsibility of making sure that the standard of patentability enunciated by the Supreme Court and by the Congress is applied in each and every case. The Supreme Court in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966), stated:

Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy. . . This is not to say, however, that there will not be difficulties in applying the nonobviousness test. What is obvious is not a question upon which there is likely to be uniformity of thought in every given factual context. The difficulties, however, are comparable to those encountered daily by the courts in such frames of reference as negligence and scienter, and should be amenable to a case-by case development. We believe that strict observance of the requirements laid down here will result in that uniformity and definitiveness which Congress called for in the 1952 Act.

Office policy is to follow *Graham v. John Deere Co.* in the consideration and determination of obviousness under 35 U.S.C. 103. As quoted above, the four factual inquiries enunciated therein as a background for determining obviousness are as follows:

- (A) Determining the scope and contents of the prior art;
- (B) Ascertaining the differences between the prior art and the claims in issue;
- (C) Resolving the level of ordinary skill in the pertinent art; and
- (D) Evaluating evidence of secondary considerations.

The Supreme Court reaffirmed and relied upon the *Graham* three pronged test in its consideration and determination of obviousness in the fact situations presented in *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 189 USPQ 449, *reh'g denied*, 426 U.S. 955 (1976) and *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 163 USPQ 673 (1969). In each case, the Court discussed whether the claimed combinations produced a "new or different function" and a "synergistic result," but it clearly decided whether the claimed inventions were nonobviousness on the basis of the three-way test in *Graham*. Nowhere in its decisions in these cases does the Court state that the "new or different function" and "synergistic result" tests supersede a finding of nonobvious

or obviousness under the *Graham* test. Accordingly, examiners should apply the test for patentability under 35 U.S.C. 103 set forth in *Graham*.

As concerns the relevance of the four patent documents to claims 6-10, 12, 40-50, the Office Action fails to render an analysis in compliance with the four *Graham* factors (see page 2 of the Office Action). No effort was made to determine to scope and contents of the prior art as it may pertain to the subject matter of claims 6-10, 12, 40-50. While some effort was made to ascertain differences between the prior art and the claims at issue, the failure to conduct a claim element by claim element analysis demonstrates the lack of making a rigorous comparison and thus the failure to comply with *Graham*. Finally, no effort was made by the Office Action to resolve the level of skill in the pertinent art. Even without showing secondary considerations, the Office Action on its face fails to comply with the first three *Graham* factors and thus warrants immediate withdrawal of the claim rejection.

In sum, the Office Action failed to abide by the *Graham* criteria on the basis that the claimed invention is somehow "merely design variations and/or intended applications of a pill product identification system". Finding an invention obvious based on a contention of "design variations" and/or "intended applications" is a fictitious contention that is not recognized by any statute, rule or regulation pertaining to obviousness. It certainly does not fit into any of the four *Graham* criteria that the Office Action quotes on page 2 and thus is necessarily improper.

Since the rejection of the claims is woefully deficient on its face, withdrawal of the rejection is warranted and requested.

Respectfully submitted,



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